

REMARKS

In the present amendment, claims 1, 5, 6, 7, 8, 9, and 19 have been amended and claim 18 has been canceled. Accordingly, claims 1-17 and 19-21 are pending in the application, with claims 1, 2, 3, 4, and 7 being independent claims. Of the pending claims, claims 1 and 5-18 are under consideration and claims 2-4 and 19-21 have been withdrawn from consideration.

Applicants note that claim 1 has been amended by including the subject matter of claim 18. Furthermore, the amendments of claims 5, 6, 7, 8, 9 have been made in order to clarify language by removing the word “substantially.”

Response to Rejection under 35 U.S.C. § 112, second paragraph

The Office Action rejects claims 1 and 5-18 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite because it is not clear what is meant with the term “substantially” in the phrase “substantially no influence” in claims 1, and 5-9.

In response, Applicants note that the term “substantially” has been deleted.

Withdrawal of the indefiniteness rejections is respectfully requested.

Response to Rejection under 35 U.S.C. § 102(a) and Double Patenting Rejection

The Office Action rejects claims 1 and 5-18 under 35 U.S.C. § 102(a) as allegedly being anticipated by U.S. Patent Application Publication No. 2005/0123532 to Kouno et al., hereinafter “KOUNO.”

The Office Action also provisionally rejects claims 1, and 7-18 over KOUNO on the ground of nonstatutory obviousness-type double patenting rejection, as allegedly being unpatentable over claims 1, 3, 10-17 and 19-25 of KOUNO.

The Examiner describes KOUNO as teaching “a method for producing a protein having a free cysteine in serum free medium.” The Examiner further recites several aspects of the method disclosed in KOUNO, for example, that the method taught in KOUNO is “carried out in the presence of a reducing agent (cysteine),” and concludes that KOUNO discloses the same method steps and all limitations as the presently claimed invention.

In response, Applicants respectfully submit that KOUNO does not teach at least one element of the presently claimed invention, i.e., adding a compound which has a disulfide bond in the molecule. Applicants note that cysteine is not a compound possessing a disulfide bond. Applicants respectfully note the difference between the α -amino acid cysteine and cystine, a molecule comprising a disulfide bond and disclosed in the present application as one of the preferred stabilizing compounds.

Applicants also refer to the present specification on page 8, second and third paragraphs, which describes the mechanism of stabilizing a protein having a free cysteine group (Pr-SH) by adding a compound comprising a disulfide group via a thiol-disulfide exchange reaction, see Reaction (I). KOUNO does not disclose such an exchange reaction. In contrast, KOUNO approaches the stabilization of the protein by adding a mild reducing agent, such as, for example, cysteine, see KOUNO column 4, paragraph [0086]. Accordingly, KOUNO and the presently claimed invention are two different approaches in order to stabilize SH-comprising proteins. Applicants note that KOUNO is also discussed in the present specification with reference to the publication of the corresponding International Application WO 03/048357, see page 9, last paragraph until page 10, first paragraph, noting that “even when a compound having a thiol group such as cysteine is present together with a protein in such a method, the reaction (I) occurs by the addition of excess cystine.”

In view of above reasons, since KOUNO does not disclose all elements of the presently claimed invention, Applicants respectfully request withdrawal of the 102(a) rejection.

As Applicants' claims require elements that are neither recited in, nor obvious over, the claims of KOUNO et al., Applicants respectfully submit that the obviousness-type double patenting should be withdrawn as well.

Response to Rejections under 35 U.S.R. § 102(b)

The Office Action rejects claims 1, 5-11, and 13 under 35 U.S.C. § 102(b) as allegedly being anticipated by Kunicki et al. (Biochemistry, 1986, Vol.25, pp. 4979-4983), hereinafter "KUNICKI."

In response, Applicants note that claim 1 has been amended to incorporate elements recited in claim 18, which was not rejected over KUNICKI. Applicants respectfully request withdrawal of the rejection over KUNICKI.

The Office Action rejects claims 1 and 5-10 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,130,418 to Thompson, hereinafter "THOMPSON."

In response, Applicants note that claim 1 has been amended to incorporate elements recited in claim 18, which was not rejected over THOMPSON. Applicants respectfully request withdrawal of the rejection over THOMPSON.

The Office Action rejects claims 1 and 5-17 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,767,246 to Hosokawa et al., hereinafter HOSOKAWA.

In response, Applicants note that claim 1 has been amended to incorporate elements recited in claim 18, which was not rejected over HOSOKAWA. Applicants respectfully request withdrawal of the rejection over HOSOKAWA.

CONCLUSION

In view of the foregoing amendment and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims. Applicants respectfully request an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
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